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TO : Commissioner for Patents
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FROM : Oleg F. Kaplun, Esq. of Fay Kaplun & Marcin, LLP

DATE : December 26, 2007

SUBJECT : Oncology
US Patent Appln. Serial No. 10/768,565
for *Pressure Actuated Safety Valve with High Flow Slit*
Inventor(s): Weaver et al.
Our Ref.: 10123/00801

NUMBER OF PAGES INCLUDING COVER: 22

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Attorney Docket No.: 10123/00801 (03-325)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

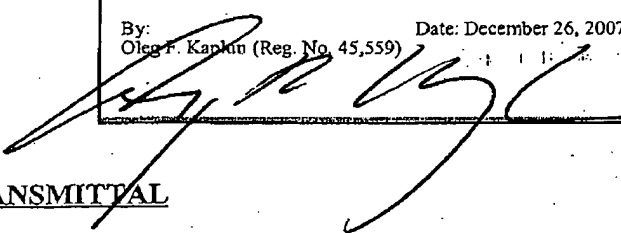
Applicant(s) : Weaver et al.
Serial No. : 10/768,565
Filed : January 29, 2004
For : Pressure Actuated Safety Valve with High Flow Slit
Group Art Unit : 3769
Confirmation No. : 6338
Examiner : Theodore J. Stigell

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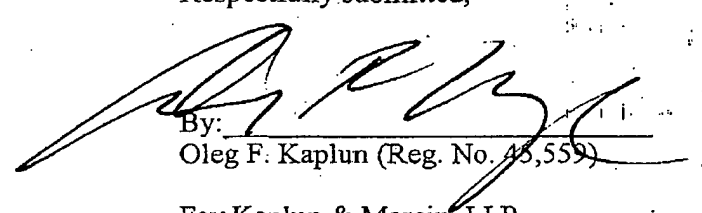
By:  Date: December 26, 2007
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Respectfully submitted,

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Attorney Docket No.: 10123/00801 (03-325)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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PATENT
Attorney Docket No.: 10123 - 00801IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Weaver et al.

Serial No.: 10/768,565

Filed: January 29, 2004

For: PRESSURE ACTUATED SAFETY
VALVE WITH HIGH FLOW SLIT

Group Art Unit: 3763

Examiner: Theodore J. Stigell

Board of Patent Appeals and
InterferencesMail Stop: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed September 25, 2007, and pursuant to 37 C.F.R. § 41.37, Appellants present this appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1-21 in the Final Office Action dated July 2, 2007. The appealed claims are set forth in the attached Claims Appendix.

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Group Art Unit: 3763
Attorney Docket No.: 10123 - 00801

1. Real Party in Interest

This application is assigned to Boston Scientific Scimed, Inc., the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected by, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 1-21 stand rejected in the Final Office Action. The final rejection of claims 1-21 is being appealed.

4. Status of Amendments

All amendments submitted by the Appellants have been entered.

5. Summary of Claimed Subject Matter

The present invention describes, in one aspect, as recited in claim 1, a pressure actuated valve 20 for controlling the flow of fluid through a medical device such as a catheter 10, wherein the valve comprises a housing 30 with a flow chamber 36 extending therethrough. (See Specification, p. 3, ¶ [0025]; Fig. 2-3). The valve 20 is further provided with a flow control membrane 32 extending across the flow chamber 36 to control the flow of fluid therethrough. (See *Id.* at p. 3, ¶ [0026]; Figs 2-3). A flow control member, such as the flow control member 100, includes a plurality of slits 104 and 106 extending therethrough and, when the flow control member 100 is acted upon by a pressure of at least a threshold magnitude, the slits open to permit fluid flow through the flow chamber 36. (See *Id.* at p. 3, ¶ [0025], [0026]; p. 4, ¶ [0033]-[0034]; Figs. 3, 5). The slits 104 and 106 of the flow control member 100 are maintained in a closed position by a biasing force applied thereto by the flow control membrane 100 preventing fluid

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flow through the flow chamber 36 when a pressure acting on the flow control member is less than the threshold magnitude. (*See Id.* at p. 4, ¶ [0033]). Furthermore, each of the slits 104 and 106 of the flow control member 100 extends between end portions 116 and 118 thereof along a curve with a minimum distance between the slits 104 and 106 occurring between a first end portion 116 and a second end 118 of these slits. (*See Id.* at p. 4, ¶ [0033]-[0034]; Fig. 5).

In another aspect, as recited in claim 10, the present invention describes a flow control device for a pressure actuated valve comprising a substantially planar elastic membrane 100 including a peripheral seating portion 102 adapted to be secured to a housing 30 of the pressure actuated valve. (*See Id.* at p.4, ¶ [0033]; Figs. 4-5). The flow control device further comprises a central portion 101 including a first curved slit 104 extending therethrough. (*See Id.* at p.4, ¶ [0033]; Fig. 4). The elastic membrane 100 biases the curved slit 104 to a closed configuration with the edges 108 and 110 in contact with one another to prevent flow therethrough. (*See Id.*). Furthermore, when the elastic membrane 104 is subjected to a pressure of at least a predetermined threshold magnitude, the elastic membrane 104 moves to an open configuration with the edges 108 and 110 of the elastic membrane 100 separated from one another so that fluid may flow therethrough. (*See Id.* at p. 4, ¶ [0034]).

In another aspect, as recited in claim 17, the present invention describes a dialysis catheter 10. (*See Id.* at p. 2, ¶ [0020]; Fig. 1). The dialysis catheter 10 comprises a catheter body having a distal end 12 insertable into a blood vessel and a proximal end connectable to a dialysis machine, wherein a lumen extends between the proximal end and the distal end 12. (*See Id.*) The dialysis catheter 10 further comprises a pressure actuated valve 20 disposed in the lumen to regulate flow therethrough and seal the dialysis catheter 10 when not in use. (*See Id.* at pp. 2-3, ¶ [0023]-[0024]; Figs. 1-3). The valve 20 further comprises a flow control membrane 32 extending across the lumen, wherein the flow control membrane 32 comprises a first curved

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slit 34 extending therethrough. (*See Id.* at p. 3, ¶ [0025]-[0026]; Figs. 1-3). When the flow control membrane 32 is not subject to a pressure of at least a predetermined threshold magnitude, the flow control membrane 32 is biased to a closed configuration in which edges of the slit 34 abut one another to prevent flow through the lumen. (*See Id.* at p. 3, ¶ [0026]; Fig. 3). When subjected to a pressure of at least a predetermined threshold magnitude, the flow control membrane 32 deforms to an open configuration with edges of the slit 34 separated from one another to allow flow through the lumen. (*See Id.* at p. 3, ¶ [0026]; Fig. 2).

In another aspect, as recited in claim 20, the present invention describes a valve for controlling flow through a medical device comprising a flow control membrane 200 extending across a lumen of the device. (*See Id.* at pp. 3-4, ¶ [0025], [0037]; Fig. 6). The flow control membrane 200 includes a plurality of slits 202, 204, 206 and 208 extending therethrough. (*See Id.* at p. 4, ¶ [0037]; Fig. 6). The slits 202, 204, 206 and 208 are configured so that, when the membrane 200 is subjected to a flow pressure of at least a threshold magnitude, the slits 202, 204, 206 and 208 open to permit flow through the lumen. (*See Id.*). Furthermore, when subjected to a flow pressure of less than the threshold magnitude, the slits 202, 204, 206 and 208 are maintained closed by a biasing force applied thereto by the membrane 200 to prevent flow through the lumen. (*See Id.*). Furthermore, each of the slits 202, 204, 206 and 208 extend between end portions thereof along a curve. (*See Id.*). A distance between a first end portion of a first one of the slits, such as slit 202, and a first end portion of a second one of the slits, such as slit 204, defines a minimum distance between the first and second slits. (*See Id.*).

In another aspect, as recited in claim 21, the present invention describes a catheter 10 comprising a flow control membrane 32 extending across a lumen thereof to regulate flow through the lumen and to seal the catheter 10 when not in use. (*See Id.*, at pp. 2-3, ¶ [0020], [0025]; Fig. 1). Extending through the membrane 21 is a first curved slit 34 configured so that,

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when the membrane 32 is subject to a flow pressure of less than a predetermined threshold magnitude, the edges of the slit 34 are held in contact with one another to prevent flow through the lumen. (*See Id.* at p. 3, ¶ [0026]; Fig. 3). Furthermore, when the membrane 32 is subject to a flow pressure of at least the predetermined threshold magnitude, the edges of the slit 34 separate from one another to permit flow therethrough. (*See Id.* at p. 3, ¶ [0026]; Fig. 2).

6. Grounds of Rejection to be Reviewed on Appeal

- I. Whether claims 1–21 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,707,357 to Mikhail et al. (hereinafter “Mikhail”)

7. Argument

- I. The Rejection of Claims 1–21 Under 35 U.S.C. § 102(b) as Anticipated by Mikhail Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1–21 were rejected under 35 U.S.C. 102(b) as anticipated by Mikhail. (*See* 7/2/07 Office Action, p. 2).

Claim 1 recites a pressure actuated valve for controlling the flow of fluid through a medical device, comprising a flow control membrane “including a plurality of slits extending therethrough, wherein, when the membrane is acted upon by a pressure of at least a threshold magnitude, the slits open to permit flow through the lumen”.

Mikhail generally describes “a palpitatable valve that may be selectively manipulated by the patient”. (*See* Mikhail, col. 6, ll. 2 - 4). The Mikhail device comprises a valve, such as valve 38 comprising a plurality of openings 76. (*See Id.* at col. 22, ll. 38-62; Fig. 5). The valve 38 is moved from a closed configuration, as shown in Figs. 3 and 4, to an open configuration, as

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shown in Fig. 5, by squeezing the wall 40 of the valve 38 radially inward, thereby causing a deformation thereof. (*See Id.* at col. 22, ll. 38-62; Figs. 3-5). Alternate embodiments of the Mikhail device disclose palpitatable valves with differently shaped openings 76 located therein the valves. (*See Id.*; Figs. 7,8, 21-35).

B. Mikhail Does Not Disclose a Pressure Actuated Valve as Recited in Claim 1

All of the valves of Mikhail are opened only through manual actuation (i.e., squeezing the valve). (*See Id.* at col. 22, ll. 38-62; Figs. 3-5). The valve of the Mikhail is designed to give a patient control over the release of urine from the bladder by remaining sealed at all times regardless of the pressure applied thereto and opening only when the patient manually opens the valve. (*See Mikhail*, col. 2, ll. 8-21.) Any opening of the valve of the valve of the Mikhail device due to fluid pressure would therefore represent a failure of the device. (*See Id.*). It is therefore respectfully submitted that Mikhail does not describe “a *pressure actuated valve*” including a flow control membrane “including a plurality of slits extending therethrough, wherein, *when the membrane is acted upon by a pressure of at least a threshold magnitude, the slits open to permit flow through the lumen,*” as recited in claim 1.

The Applicants respectfully disagree with the Examiner’s contention that claim 1 does not include any limitations requiring that the valve be opened by fluid pressure. Claim 1 clearly recites a “pressure actuated valve” including “a fluid control membrane” including slits opening when the membrane is “acted upon by a pressure of at least a threshold magnitude.” It is respectfully submitted that, as made clear by the preamble to the claim and as made further clear by the specification which describes only fluid pressures as opening the disclosed valves, the “pressure” recited in claim 1 is fluid pressure. Furthermore, as described in detail in the

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specification, the pressure of a "predetermined magnitude" is a fluid pressure sufficient to separate the edges of the slit in the membrane. No other type of pressure (e.g., manual pressure) is ever shown or suggested in the claim as opening the valve. Throughout the specification, the terms pressure and flow pressure are used interchangeably and thus, it is submitted that the recitation in claim 1 of "[a] pressure actuated valve for controlling the flow of fluid through a medical device," which includes "a flow control membrane [...] including a plurality of slits extending therethrough, wherein, when the membrane is acted upon by a pressure of at least a threshold magnitude, the slits open to permit flow through the lumen," clearly refers to a fluid pressure.

The Examiner also contends that there must be a flow pressure at which the valve of Mikhail must open. However, Mikhail describes "a palpitatable valve that may be selectively manipulated by the patient." (See Mikhail, col. 6, ll. 2 - 4). That is, the valves of Mikhail are opened only through manual actuation by squeezing the valve. Mikhail does not contemplate or suggest that the palpitatable valve can be opened by fluid pressure. There is no reason whatsoever to assume that the palpitatable valve could successfully open in response to "a pressure of at least a threshold magnitude," as recited in claim 1 nor is there any reason to assume that such an opening would not represent a failure of the valve. It is noted that a modification to a device may only be applied where there is some teaching, suggestion, or motivation to do so. (See *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335, Fed. Cir. 2006.) Mikhail describes a process by which the palpitatable valve opens in response to *inward radial pressure*, which is exerted by *manual squeezing*. (*Id.* at col. 22, lines 42 - 62). Thus, Mikhail's valve is specifically designed to open using manual pressure. The use of fluid pressure is completely against the teachings of Mikhail, as the device is designed to retain urine by

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resisting the natural pressure of bladder fluid. (*Id.* at col. 2, lines 8 - 21). In fact, Mikhail specifically teaches away from the use of predetermined operational pressure ranges. (*Id.*). Any opening of this valve due to fluid pressure would cause leakage and would represent a failure of the valve. Thus, Mikhail teaches against opening in response to any kind of fluid pressure. In addition to being undesirable, the opening of the valve in response to fluid pressure would necessarily represent a failure of Mikhail's device, indicating a structural or material defect, since opening to fluid pressure would never happen under normal circumstances. It is further submitted that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. (*See In re Gordon*, 733 F.2d 900, 221 USPQ 1125, Fed. Cir. 1984). Assuming it were possible to open the valve using a sufficient fluid pressure, such force would indicate that Mikhail's device was damaged, which completely defeats the entire purpose of Mikhail's device. Furthermore, it is respectfully submitted that a reading of the prior art which equated the fact that all structures must eventually fail under some fluid pressure with a pressure activated valve completely reads these pressure related limitations out of the claim. Of course, even steel bulkhead doors and dams will open under some fluid pressure. However, it is clear that this does not make them pressure activated valves.

For these reasons, it is respectfully submitted that Mikhail neither discloses nor suggests a *pressure actuated* valve for controlling the flow of fluid through a medical device, the valve comprising a flow control membrane "including a plurality of slits extending therethrough, wherein, *when the membrane is acted upon by a pressure of at least a threshold magnitude, the slits open to permit flow through the lumen,*" as recited in claim 1.

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Furthermore, it is noted that claim 1 recites a plurality of slits "wherein each of the slits extends between end portions thereof along a curve and *wherein a distance between a first end portion of a first one of the slits and a first end portion of a second one of the slits is a minimum distance between the first and second slits.*" This configuration of slits is most simply illustrated by Fig. 5 of the instant application. In contrast, none of the slit configurations shown in Mikhail shows or suggests this limitation. Thus, it is respectfully submitted that none of the valves disclosed by Mikhail disclose or suggest a plurality of slits "wherein each of the slits extends between end portions thereof along a curve and wherein a distance between a first end portion of a first one of the slits and a first end portion of a second one of the slits is a minimum distance between the first and second slits," as recited in claim 1 and that claim 1 is therefore allowable over Mikhail. Because claims 2 - 9 depend from, and, therefore, include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 10 recites substantially similar limitations, including a flow control device for a pressure actuated valve, comprising "*a substantially planar elastic membrane including a peripheral seating portion adapted to be secured to a housing of the pressure actuated valve and a central portion including a first curved slit extending therethrough, the elastic membrane biasing the first slit to a closed configuration in which edges of the first slit are in contact with one another to prevent flow past the membrane, wherein, when the membrane is subject to a pressure of at least a predetermined threshold magnitude, the membrane moves to an open configuration in which the edges of the first slit are separated from one another so that fluid may flow past the membrane through the first slit.*" It is therefore respectfully submitted that this claim is allowable for the same reasons stated above in regard to claim 1.

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In addition, it is noted that each of the valves of Mikhail is a "dome-type" valve. (*See* Mikhail, col. 27, ll. 6-55; Fig. 3). Specifically, the valves of the Mikhail device are dome shaped and are not "substantially planar", as recited in claim 10. The Examiner asserts that the term "planar" means lying in a plane. However, the Examiner's reading which forces a domed valve into this definition is inconsistent with the common definition of the term planar, which means flat or level. This definition of planar is well-known to those skilled in the art and is even used repeatedly throughout Mikhail. For instance, Mikhail describes a mandril with a "generally flat or planar section" and deforming the valve into a "flat or planar configuration." (*See* Mikhail, col. 24, ll. 44 - 60). Thus, it is respectfully submitted that Mikhail neither discloses nor suggests "a substantially planar elastic membrane," as recited in claim 10 and that claim 10 is allowable for at least this additional reason. Because claims 11 - 16 depend from, and, therefore, include all of the limitations of claim 10, it is respectfully submitted that these claims are also allowable.

Claim 17 recites a catheter comprising "a pressure actuated valve" including a flow control membrane extending across the lumen, the membrane including a first curved slit extending therethrough, "*wherein when the membrane is subject to a pressure of at least a predetermined threshold magnitude, the membrane deforms to an open configuration in which edges of the first slit separate from one another to allow flow through the lumen.*" It is respectfully submitted that claim 17 is allowable for the same reasons stated above in regard to claim 1. Because claims 18 and 19 depend from, and, therefore, include all of the limitations of claim 17, it is respectfully submitted that these claims are also allowable.

Claim 20 recites a valve including "a flow control membrane extending across a lumen of the device, the membrane including a plurality of slits extending therethrough, the slits being

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configured so that, *when the membrane is subjected to a flow pressure of at least a threshold magnitude*, the slits open to permit flow through the lumen". It is respectfully submitted that claim 20 is allowable for the same reasons stated above in regard to claim 1.

Claim 21 recites a catheter including "a flow control membrane extending across a lumen thereof to regulate flow through the lumen and to seal the catheter when not in use, the membrane including a first curved slit extending therethrough, the slit being configured so that... *when the membrane is subject to a flow pressure of at least the predetermined threshold magnitude*, the edges of the slit separate from one another to permit flow past the membrane." It is respectfully submitted claim 21 is allowable for at least the same reasons stated above in regard to claim 1.

8. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 102(b) and indicate that claims 1-21 are allowable.

Respectfully submitted,

Date: 12/26/07

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CLAIMS APPENDIX

1. (Original) A pressure actuated valve for controlling the flow of fluid through a medical device, the valve comprising:
 - a housing including a lumen extending therethrough; and
 - a flow control membrane extending across the lumen to control the flow of fluid through the lumen, the membrane including a plurality of slits extending therethrough, wherein, when the membrane is acted upon by a pressure of at least a threshold magnitude, the slits open to permit flow through the lumen and, when not acted upon by a pressure of at least the predetermined magnitude, the slits are maintained closed by a biasing force applied thereto by the membrane to prevent flow through the lumen, wherein each of the slits extends between end portions thereof along a curve and wherein a distance between a first end portion of a first one of the slits and a first end portion of a second one of the slits is a minimum distance between the first and second slits.
2. (Original) The valve according to claim 1, wherein the first slit extends along a portion of a curve having a first radius of curvature and the second slit extends along a portion of a curve which is substantially a mirror image of the curve along which the first slit extends
3. (Original) The valve according to claim 2, wherein the plurality of slits includes a third slit having a third radius of curvature different from the first radius of curvature.
4. (Original) The valve according to claim 1, wherein the first and second slits are disposed substantially symmetrically about a line of symmetry of the membrane.

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5. (Original) The valve according to claim 4, wherein the membrane is substantially elliptical and the line of symmetry is a major axis of the membrane.
6. (Original) The valve according to claim 4, wherein the membrane is substantially circular and the line of symmetry is a diameter of the membrane.
7. (Original) The valve according to claim 1, wherein the first and second slits are disposed substantially symmetrically about a point of symmetry of the membrane.
8. (Original) The valve according to claim 7, wherein the point of symmetry is a center of the flow control membrane.
9. (Original) The valve according to claim 1, wherein the first and second slits are spaced from one another by a distance sufficient to prevent contact between edges of the first and second slits when they are open.
10. (Original) A flow control device for a pressure actuated valve, comprising a substantially planar elastic membrane including a peripheral seating portion adapted to be secured to a housing of the pressure actuated valve and a central portion including a first curved slit extending therethrough, the elastic membrane biasing the first slit to a closed configuration in which edges of the first slit are in contact with one another to prevent flow past the membrane, wherein, when the membrane is subject to a pressure of at least a predetermined threshold magnitude, the membrane moves to an open configuration in which the edges of the first slit are separated from one another so that fluid may flow past the membrane through the first slit.

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11. (Original) The flow control device according to claim 10, wherein the first slit extends substantially along a portion of a circle having a radius of curvature selected to achieve a desired flow opening area when subject to the predetermined threshold pressure.
12. (Original) The flow control device according to claim 10, wherein the membrane further includes a second curved slit extending through the central portion, wherein the first and second slits are separated by a distance sufficient to prevent contact between the edges of the first slit and edges of the second slit when the first and second slits are in the open configuration.
13. (Original) The flow control device according to claim 10, wherein the elastic membrane is a polymeric membrane.
14. (Original) The flow control device according to claim 12 wherein the first and second slits are disposed substantially symmetrically about a line of symmetry of the membrane.
15. (Original) The flow control device according to claim 14, wherein the membrane is substantially elliptical and wherein the line of symmetry is one of a major and a minor axis of the membrane.
16. (Original) The flow control device according to claim 14, wherein the membrane is substantially circular and wherein the line of symmetry is a diameter of the membrane.
17. (Original) A dialysis catheter comprising:

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a catheter body having a distal end insertable into a blood vessel, a proximal end connectable to a dialysis machine and a lumen extending between the proximal and distal ends; and

a pressure actuated valve disposed in the lumen to regulate flow therethrough and to seal the catheter when not in use, wherein the valve includes a flow control membrane extending across the lumen, the membrane including a first curved slit extending therethrough, wherein, when the membrane is not subject to a pressure of at least a predetermined threshold magnitude, the membrane is biased into a closed configuration in which edges of the first slit abut one another to prevent flow through the lumen and, when the membrane is subject to a pressure of at least a predetermined threshold magnitude, the membrane deforms to an open configuration in which edges of the first slit separate from one another to allow flow through the lumen.

18. (Original) The dialysis catheter according to claim 17, wherein the membrane further comprises a second curved slit, wherein the first and second slits are separated by a distance sufficient so that, when the membrane deforms to the open configuration, the edges of the first slit do not contact edges of the second slit.

19. (Original) The dialysis catheter according to claim 17, wherein the predetermined threshold magnitude corresponds to a pressure that would be induced within the lumen by connection of an operating dialysis machine to the proximal end and, wherein the predetermined threshold magnitude is substantially greater than pressure that would be induced by action of a patient's vascular system.

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20. (Previously Presented) A valve for controlling flow through a medical device, the valve comprising a flow control membrane extending across a lumen of the device, the membrane including a plurality of slits extending therethrough, the slits being configured so that, when the membrane is subjected to a flow pressure of at least a threshold magnitude, the slits open to permit flow through the lumen and, when subjected to a flow pressure of less than the threshold magnitude, the slits are maintained closed by a biasing force applied thereto by the membrane to prevent flow through the lumen, each of the slits extending between end portions thereof along a curve and wherein a distance between a first end portion of a first one of the slits and a first end portion of a second one of the slits defines a minimum distance between the first and second slits.

21. (Previously Presented) A catheter comprising a flow control membrane extending across a lumen thereof to regulate flow through the lumen and to seal the catheter when not in use, the membrane including a first curved slit extending therethrough, the slit being configured so that, when the membrane is subject to a flow pressure of less than a predetermined threshold magnitude, edges of the slit are held in contact with one another through a bias of the membrane to prevent flow past the membrane and, when the membrane is subject to a flow pressure of at least the predetermined threshold magnitude, the edges of the slit separate from one another to permit flow past the membrane.

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EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

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RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.